

Long-term Results in the Treatment of Menorrhagia and Hypermenorrhea With a Thermal Balloon Endometrial Ablation Technique

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ABSTRACT

Background and Objectives: Evaluation of long-term results using a thermal balloon endometrial ablation technique to treat menorrhagia and hypermenorrhea, considered dysfunctional uterine bleedings.

Methods: A single-arm, prospective study with long-term follow-up of 48 months at the department of obstetrics and gynecology, University of Kiel, Germany. Following hysteroscopic evaluation of the uterine cavity and fractionated curettage, the Cavaterm endometrial thermal ablation technique was performed on 70 patients over the age of 40 with menorrhagia and hypermenorrhea in whom medical treatment had previously failed. The study included a group of 10 patients with adenomyosis and uterine fibroids.

Results: In 65 patients, a complete 48-month follow-up evaluation was possible: 58% of patients reported amenorrhea and 33% hypomenorrhea. Nine percent of patients remained eumenorrheic. Fifty percent of the small group with failed indications for the procedure had to undergo a hysterectomy.

Conclusions: The Cavaterm thermal coagulation system in the earlier mode of application (15 minutes at a temperature of 70°C and a pressure of 200 mm Hg) is a safe and highly effective method of endometrial ablation resulting in a minimal amount of posttreatment menstrual bleeding.

Key Words: Thermal balloon, Endometrial ablation, Cavaterm™ system, Long-term results.

INTRODUCTION

By 1937 Badenheuer¹ had already published a paper on electrocoagulation of the endometrium to treat dysfunctional uterine bleeding. After Lindemann² introduced hysteroscopy, using the resectoscope for hysteroscopic endometrial ablation, this technique became widely accepted. In 1981 Goldrath³ et al applied laser energy for endometrial ablation. In rollerball electrocoagulation, electrosurgical resection of the endometrium is essentially performed.⁴⁻⁶

Because of the thickness of the endometrium, pretreatment with GnRH analogues has been widely discussed and applied. When fluid distension is used for hysteroscopy, the view is often obscured by debris and bleeding. There can be serious complications of fluid overload and electrolyte imbalance. To avoid this problem, Goldrath³ performed CO₂ hysteroscopy with YAG laser ablation. This technique appeared to be extremely skill intensive.

Our group has had broad experience with the Cavaterm technique of thermal coagulation of the endometrium, a balloon technique for endometrial ablation that is easy to perform and very effective.

METHODS

We designed a prospective, single-arm study to evaluate the efficacy of the Cavaterm™ system. Women beyond the age of 40 requiring endometrial ablation for menorrhagia and hypermenorrhea were included in the study, with the requirement that hormonal treatment for their bleeding had previously failed.

Patients were divided into 2 groups. Group A was a small group of 10 patients with adenomyosis and an enlarged fibroid uterus in addition to menorrhagia and hypermenorrhea. These patients were informed preoperatively that the effectiveness of the procedure could not be guaranteed but that a successful endometrial ablation would rule out the necessity for performing a hysterectomy. If the endometrial ablation failed, a hysterectomy would have to be performed. Group B consisted of 60 patients with normal pap smears, no distortion of the

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uterine cavity, no polyps or myomas in the uterine cavity, no pelvic inflammatory disease, and no long-term steroid use. Patients were contacted at 3, 9, and 48 months postablation to assess their bleeding behavior and well-being.

All procedures were carried out with patients under general anesthesia. No specific postoperative medication was applied.

Cavaterm Balloon Application

The Cavaterm™ plus system consists of a balloon catheter that utilizes a combination of heat, pressure, and circulation to destroy the endometrium and the underlying myometrium to a depth of 6-8 mm. This simple, painless treatment takes 8-15 minutes. After hysteroscopic examination of the uterine cavity, dilation and curettage is performed, the cavity length measured, and the catheter adjusted to the cervical length. No coagulation takes place within the cervix. After the balloon has been inserted, it is inflated to 200 mm Hg; and heat circulation (regulated by the Cavaterm central unit) is initiated for 10 minutes. The balloon is then deflated and removed from the uterus, and the treatment is terminated (Figures 1-3).

RESULTS

Data from 70 patients treated between 1996 and 2000 at our department were evaluated 3 and 48 months after the procedure. The bleeding pattern of the 70 patients after 3 months and 9 months and of the remaining 65 patients after 4 years is shown in Figure 4. The treatment out-

come according to age shows a remaining cyclic function in patients older than 50 years mainly due to hormonal replacement therapy.

The 48-month evaluation of bleeding patterns in the 65 patients is shown in Table 1. Five patients in group A underwent a hysterectomy because of continuous bleeding. For 50% of patients in group A who underwent this treatment to avoid a hysterectomy, the Cavaterm endometrial ablation technique was effective. After 48 months, the bleeding status of the 60 patients (including the hormonal replacement therapy patients) with a correct indication for endometrial ablation by Cavaterm was amenorrhea 58%, hypomenorrhea (a substantial decrease in blood flow) 33%. Nine percent of patients were clas-

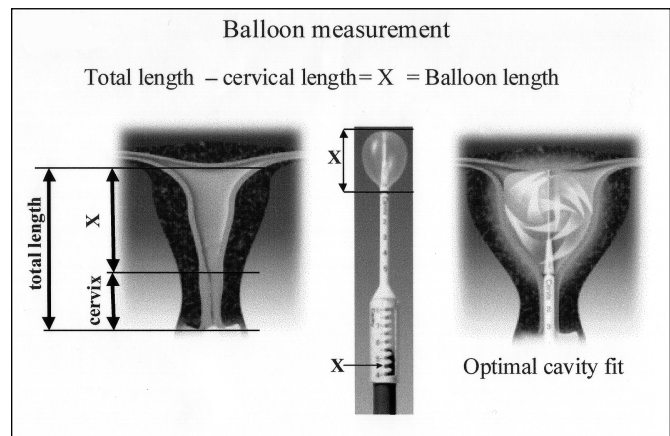


Figure 1. Cavaterm™ plus system, detailing balloon measurement and optimal cavity fit.

Table 1.
Outcome 48 Months After Thermal Balloon Coagulation of Endometrium in 2 Groups of Patients

	Group A (n = 10)		Group B (n = 60)	
	n	%	n	%
Hysterectomies following failures (n = 5)	5	50	-	-
Bleeding patterns at 48 months (n = 65)				
Amenorrhea	-	-	35	58
Hypomenorrhea	5	50	20	33
Eumenorrhea	-	-	5	9

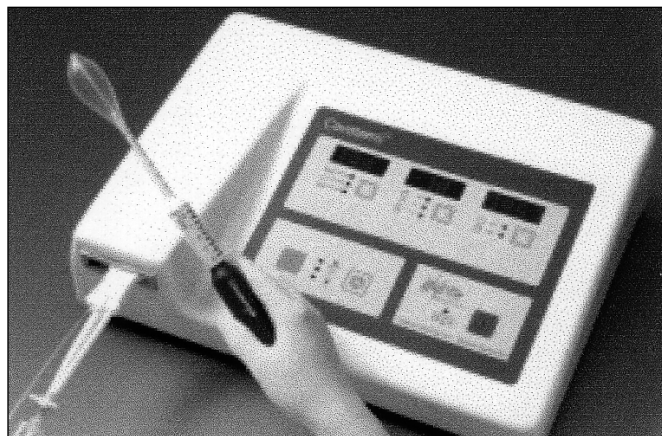


Figure 2. Cavaterm™ central unit for the regulation of heat and pressure.

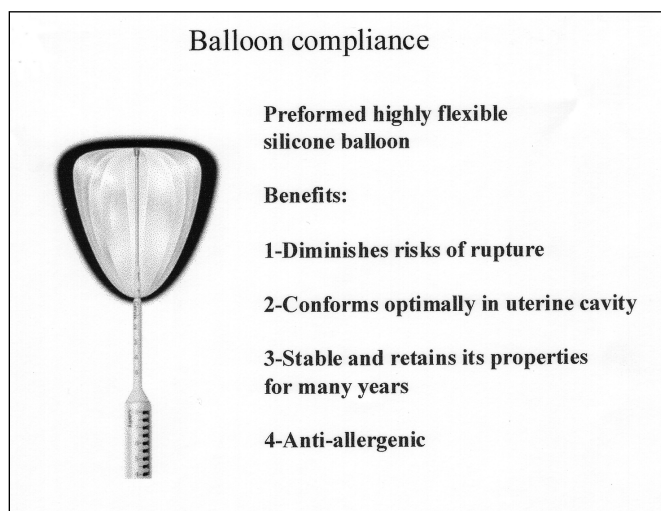


Figure 3. Cavaterm™ balloon compliance.

sified as eumenorrheic and showed a regularity of menstruation compared with the previous menorrhagia and hypermenorrhea. The 2-year review demonstrates the durability of the bleeding reduction with the Cavaterm system.

The probability of amenorrhea was found to increase with age (**Figure 5**).

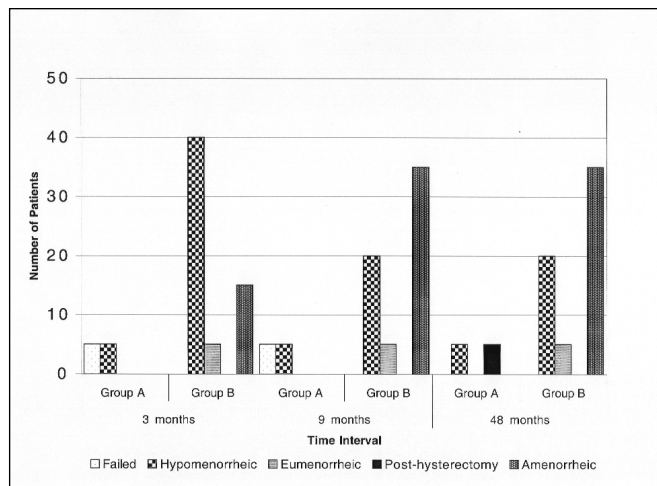


Figure 4. Bleeding pattern in 70 patients over 48 months.

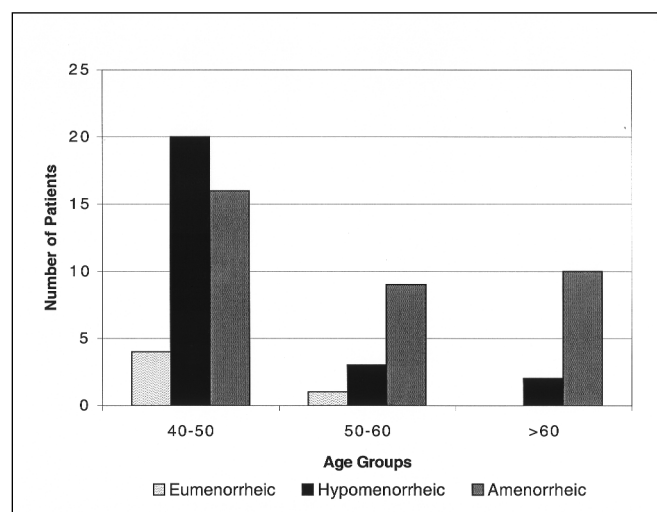


Figure 5. Bleeding pattern 48 months after Cavaterm endometrial ablation according to age at time of treatment.

Complications

No intraoperative or postoperative complications were encountered with the Cavaterm system, and none were reported within the observation period of 4 years. All patients were treated on an inpatient basis and discharged on the following day or the day after according to the regulations of our hospital. No postoperative inflammation occurred, and no reports of specific pain were made. On the contrary, we found an overall high

satisfaction rate and good acceptance in our collective patients.

DISCUSSION

On reviewing the literature on traditional hysteroscopic techniques and the vast number of endometrial ablation reports, especially endometrial resection for the treatment of menorrhagia,⁷ hysterectomy after endometrial ablation is only indicated in specific cases.⁸ Follow-up reports over a period of more than 5 years exist. Thermoregulated endometrial ablation reports over a 4-year period, as described in this paper, compare favorably with hysteroscopically-guided laser or electrosurgical ablation. Pretreatment with GnRH agonists, if a curettage is performed, as in our cases, remains open to discussion.^{9,10} Long-term results do not appear to be dependent upon preoperative GnRH agonist treatment.

A recent study by Gallinat and Cosgriff¹¹ shows favorable outcomes with the Vesta™ system, which allows for precise regional delivery of radiofrequency energy, assuring a thorough and safe treatment of the entire uterine cavity. Our results with the Cavaterm balloon compare favorably with those of Gallinat's study. The Cavaterm balloon seems to ideally adjust itself to the uterine cavity; and the applied pressure, heat, and vibration deliver a smooth heat attack to the endometrium. Our postoperative hysteroscopic controls always showed a smooth, brownish coagulated endometrium, and the ostia remained untouched in almost all cases.

Numerous global ablation systems exist, including cryoablation, hydro-thermal ablation,¹² interstitial laser heating,¹³ microwave,¹⁴ an intrauterine hormone delivery device,¹⁵ and the Vesta electroballoon application.¹¹ The water balloon systems that use either glucose or fructose as a distension medium¹⁶⁻¹⁸ seem to be sophisticated in their application. Precise energy delivery can be controlled, and computer software provides a safe and efficient treatment for dysfunctional uterine bleeding including hypomenorrhea and amenorrhea. Patients must be carefully selected for the treatment, which promises to be effective if patients meet the screening requirements. Favorable results and convincing evidence speak for the application of the Cavaterm balloon catheter system.

CONCLUSIONS

The evaluation of long-term results with the thermal balloon endometrial ablation technique of Cavaterm for the treatment of menorrhagia and hypermenorrhea for dysfunctional uterine bleeding proved to be an effective method resulting in a minimal amount of posttreatment menstrual bleeding. We found that the Cavaterm thermal coagulation system in the earlier mode of application (15 minutes at a temperature of 70°C and a pressure of 200 mm Hg) was highly successful. In 65 of the selected patients, a complete 48-month follow-up was possible. In this group, 58% reported amenorrhea, 30% hypomenorrhea, and 9% of patients remained amenorrheic. These results speak for the effectiveness of the Cavaterm system. In view of the new Cavaterm plus system with a shorter and better-regulated coagulation, even better results are expected.

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